

Appl. No. 10/814,444
Amendment dated March 7, 2005
Reply to Office Action of December 8, 2004

REMARKS/ARGUMENTS

The Examiner has rejected Claims 1 - 11 under 35 USC 102 and has rejected Claims 12, 13, 16 - 18 under 35 USC 103. The Examiner has indicated that Claims 14, 15, 19 and 20 are allowable and that Claims 21 - 23 would also be allowable if rewritten to overcome the rejection under 35 USC 112. Accordingly, Claim 14 has been made independent to include the limitations of its base claims so that it is in allowable condition. Claim 15 is dependent on Claim 14 and therefore should be allowable. Claims 19 and 20 are canceled. Claim 21 has been placed in independent form and has been rewritten to overcome the rejection under 35 USC 112 so that it should also be allowable. Claims 22 and 23 have been canceled.

Claims 1 - 11 have been rejected under 35 USC 102 as being anticipated by Jackson et al., Yeo et al. and Hartl et al. Claims 2, 4, 5 and 9 - 11 have been canceled. Claims 1 and 6 have been amended to overcome these rejections. In particular, each of Claims 1 and 6 have been amended to include non-human peroxidase-acting constituents as part of the mixture. Hartl et al. does not teach the use of non-human peroxidase-acting constituents as a component of a synthetic stool material. Instead, Hartl et al. teaches the inclusion of hemolyzed human blood for use as a positive control. Since hemolyzed human blood presents a significant biohazard risk to technicians who must handle the material, the present invention represents an improvement that was not anticipated by Hartl et al. It is asserted that Jackson et al., Yeo et al. and Kubiak et al. are of little relevance to the claims as amended because the cited inventions are for use in disposable absorbent personal care items such as diapers and the like. As such, the teachings of

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these citations do not contain any sort of peroxidase-acting material or hemoglobin. With regard to Rao et al., the invention thereof is directed to an article for insertion into the body for use in evaluating anorectal function and thus comprises inert materials including silicon gel having no human or non-human blood products. Yoshizawa et al. and Hartl et al. do disclose the use of human blood products, but neither suggests the use of non-human blood products. Yoshizawa et al. does teach the use of hemoglobin but includes a stabilizer, namely EDTA. Since EDTA is not compatible with some of the fluorescent-based immunoassays that are used with the present invention, the Yoshizawa et al. formulation is not optimal for use as a positive control in immunoassays and, in fact, the Yoshizawa et al. invention was designed instead for training laboratory personnel in the use of equipment for the collection and handling of feces and not for use in assays. Applicant requests that the rejections of Claims 1 and 6 under 35 USC 102(b) be withdrawn. Because Claims 3 and 8 depend from amended Claims 1 and 6, respectively, Applicant requests that the rejections of Claims 3 and 8 under 35 USC 102(b) also be withdrawn. Applicant believes that the patentable aspects of the present invention are broader than merely the ratio ranges claimed in the narrower claims; and as far as Claims 1, 3, 6, 8 and 17, Applicant asserts that the inclusion of a non-human peroxidase-acting component in an artificial feces material intended for use in testing of human specimens is novel and unobvious.

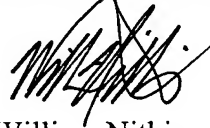
Claims 12, 13 and 16 - 18 are rejected under 35 USC 103(a) as being unpatentable over Hartl et al. Claims 12, 13, 16 - 18 have been canceled.

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Applicant has added new Claims 24 - 26 to depend from amended Claim 6, and new Claims 28 and 29 to depend from amended Claim 14. Applicant requests that they be allowed.

It is urged that the amended claims overcome the rejections and that the pending claims are allowable. It is requested that the pending claims be allowed and that a Notice of Allowance issue in due course.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William Nitkin', is written over a horizontal line.

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